introducing a second substance stream through a septum and into the third flow channel, the second and third flow channels intersecting into the first flow channel such that the first and second substance streams pass together out of the first flow channel, passing into the patient through the housing and infusion cannula.

22. (Canceled)

23. (Canceled)

REMARKS

Claims 1 to 21 are currently pending and stand rejected.

Objection to the Drawings:

The drawings were objected to as not showing the first, second and third flow channels as set forth in claims 2 to 5.

This rejection is not understood, as follows. The first, second and third flow channels together form the internal Y-shaped flow channel structure of the device. Specifically, bore 286[1] and flow channel 505[2] (see Fig. 10) both intersect and connect to flow channel 290[3] (see Fig. 11) thereby forming the internal Y-shaped (i.e. 3-branch) flow channel structure of the device.

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[1] the second flow channel.

[2] the third flow channel.

[3] the first flow channel.

Section 112 Rejections:

Minor antecedent basis informalities had been noted by the Examiner in claims 8, 14 and 17.

Suitable correction has been made to correct these informalities. However, the Examiner's conclusion that there is insufficient antecedent basis for "a target area" in line 3 of claim 17 is not understood. Specifically, the term "a target area / tissue" is first introduced in the preamble to the claim, and then "a target area / tissue" is recited in line 3 of the claim. Reconsideration of this objection is therefore respectfully requested.

Section 102 and 103 Rejections:

Claims 1 to 8, 11, 12, 15 to 18, 22 and 23 were rejected as being anticipated by Leinsing '446.

Claims 9, 10, 13, 14, 19, 20 and 21 were rejected as being obvious over Leinsing '446 in view of Funderbunk '718.

In setting forth these rejections, Leinsing was relied upon as teaching a Y-shaped flow channel structure, while Funderbunk was relied upon as teaching a hub connected to a housing using a fastener with fingers, a connection with pins and bores, and a septum in the housing.

(a) The Presently Claimed Invention:

The present invention provides a system in which two different medication flow streams merge into a single flow stream which is then delivered through a single infusion cannula into a patient.

The present invention is ideally suited for use by diabetic patients. This is due to the fact that diabetics often require both a continuous supply of insulin throughout the day, and supplemental periodic bolus injections of insulin at specific times in the day. Therefore, what many diabetic patients do is receive their continuous insulin delivery through a infusion tube connected to an insulin pump while using a separate syringe needle to deliver their supplemental bolus injections.

The present invention instead provides a system where a patient may be infused independently from two different sources (i.e. independently by syringe and pump) through a single infusion cannula. For example, in accordance with the present invention, the patient simply needs to inject the syringe needle into the third flow channel in the housing. The bolus medication then flows from the syringe and mixes with the medication delivered into the second flow channel, which together passes out of the first flow channel and into the patient.

The present invention comprises two parts: (a) a housing[4], and (b) a connecting hub[5]. The housing is positioned directly against the patient's skin and the connecting hub (having the internal Y-shaped flow structure therein) is then attached onto the distal end of the housing.

Claims 1 and 17 have now been amended to set forth the *housing* portion of the device having a *generally flat bottom for positioning against a patient's skin.* This feature of the invention is most clearly seen in Fig. 7, as follows. Flattened bottom 268 is

[4] element 202 in Fig. 2.

[5] element 206 in Fig. 2.

positioned against the patient's skin such that cannula 204 (which is positioned at angle Beta to flat bottom 268) angles downwardly and thus penetrates through the patient's skin.

A particular attribute of the present two-part design is that when the connecting hub is connected to the housing, the second and third flow streams in the connecting hub intersect with the first flow channel at a location that is very close to the patient (i.e. being adjacent to the housing positioned directly on the patient's skin) Thus, when medication is injected into the third flow channel, it enters the patient very quickly. Moreover, since the housing is positioned directly on the surface of the patient's skin, it provides a stable platform so that it is very easy for an operator to simply inject a syringe needle into the third flow channel at the back end of the connecting hub.

Secondly, since the Y-shaped flow structure is within the connector hub (as opposed to being within the housing) it is very easy to disconnect and safely plug the medication delivery path into the patient through cannula 204 when desired. For example, it is particularly desirable for a patient to temporarily disconnect an infusion pump and line when showering. With the present design, connector hub 206 (Figs. 1 and 2) is simply disconnected from housing 202 (Fig. 3). Housing 202 remains positioned on the surface of the patient's skin. Plugging system 330 (Fig. 15) is then connected to housing 202 (in place of connector hub 206).

As can be appreciated, it is easy to seal the *single* flow pathway into the patient (i.e. the flow pathway through cannula 204). An attribute of this design is that the single flow opening into the patient can easily be plugged (i.e. "sealed") when the connecting hub is temporarily disconnected. This reduces the potential for contamination or infection. When

it is desirable to re-connect the infusion pump and line, plugging system 330 is then simply disconnected from housing 202 and connector hub 206 is simply re-connected to housing 202. Thus, the a insulin delivery system can be conveniently disconnected and re-connected to the patient without even having to disturb the medication delivery cannula (204) that enters the patient.

(b) The Cited Art Distinguished:

As explained above, the presently claimed invention has numerous attributes not seen in the prior art. In contrast, Leinsing simply provides a standard Y-shaped connector that is positioned some distance away from the patient. Leinsing's connector is not positioned at or near the surface of a patient's skin at all. Funderbunk offers none of the novel properties of the present Y-shaped design, let alone the presently claimed two-part system of a housing and a connecting hub, with the Y-shaped flow channel being specifically disposed within the connecting hub portion of the device.

Conclusion:

For the reasons presented above, all claims are believed to be in condition for allowance. A Notice of Allowance is therefore respectfully requested.

Should the Examiner feel that a telephone conference would advance prosecution of the present application, he is invited to call the undersigned attorney at the number listed below.

Respectfully submitted,

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VERSION MARKED TO SHOW CHANGES MADE

1. (Amended) An infusion system, comprising:
a housing having a generally flat bottom for positioning against a patient's skin; and
a connecting hub which is attachable to the housing, the connecting hub having an internal Y-shaped flow channel structure.

2. (As filed) The system of Claim 1, wherein the internal Y-shaped flow channel structure comprises:
a first flow channel adapted to connect to a proximal end of an infusion cannula;
a second flow channel adapted to connect to a distal end of an infusion delivery tube; and
a third flow channel which is covered by a septum, the first, second and third flow channels all intersecting within the connecting hub.

3. (As filed) The system of Claim 2, wherein the first flow channel exits from a distal end of the connecting hub.

4. (As filed) The system of Claim 2, wherein the second flow channel exits from a proximal end of the connecting hub.

5. (As filed) The system of Claim 2, wherein the third flow channel exits from a proximal end of the connecting hub.

6. (As filed) The system of Claim 2, further comprising:
an infusion cannula received into the distal end of the housing.

7. (As filed) The system of Claim 2, wherein the second flow channel is adapted to receive a distal end of the infusion delivery tube therein.

8. (Amended) The system of Claim 1, wherein the connecting hub is attached to a **[the]** proximal end of the housing.

9. (As filed) The system of Claim 8, wherein the connecting hub is attached to the proximal end of the housing by a pair of fasteners.

10. (As filed) The system of Claim 9, wherein each fastener comprises a finger on one of the housing and connecting hub, and a cantilevered lever on the other of the housing and connecting hub.

11. (As filed) The system of Claim 2, wherein the connecting hub further comprises:
a hollow tube being received into the first flow channel and projecting from the distal end of the connecting hub, the hollow tube being dimensioned to be received within a channel passing through the housing.

12. (As filed) The system of Claim 11, where the channel passing through the housing is tapered.

13. (As filed) The system of Claim 2, wherein the volume of the third flow channel is less than 100 microliters.

14. (Amended) The system of Claim 1, further comprising:
at least one pin or bore on a **[the]** distal end of the connecting hub, and at least the other of the pin or bore on a **[the]** proximal end of the housing, the at least one pin being receivable into the at least one bore when the housing and the connecting hub are connected together.

15. (As filed) The system of Claim 4, further comprising:
an infusion delivery tube in fluid communication with the second flow channel.

16. (As filed) The system of Claim 15, wherein the infusion delivery tube is received into the second flow channel.

17. (Amended) A method of infusing two different medication streams into a target area/ tissue in a patient through a single subcutaneous pathway, comprising:
inserting a distal end of an infusion cannula into a target area / tissue, the infusion cannula being supported by a housing at its proximal end, the housing having a generally flat bottom for positioning against a patient's skin;
attaching a connecting hub to the housing, the connecting hub having an internal Y-shaped flow channel structure comprising first, second and third flow channels which intersect within the connecting hub;
introducing a first substance stream through a delivery tube and into the second flow channel; and
introducing a second substance stream through a septum and into the third flow channel, the second and third flow channels intersecting into the first flow channel such that the first and second substance streams pass together out of the first flow channel, passing into the patient through the housing and infusion cannula.

18. (As filed) The method of Claim 17, wherein the second substance stream is injected through the septum by a syringe.

19. (As filed) The method of Claim 17, further comprising:
disconnecting the connecting hub from the housing; and
attaching a plugging system to the housing while leaving the distal end of the infusion cannula within the patient.

20. (As filed) The system of Claim 1, further comprising:
a septum positioned within the housing.

21. (As filed) The system of Claim 20, further comprising:
a funnel shaped guide positioned at a proximal end of the septum.

22. (Canceled)

23. (Canceled)